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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,887	09/14/2006	Jakob Busch-Petersen	PU60790	1742
20462 7590 10/06/2008 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER COLEMAN, BRENDA LIBBY				
ART UNIT		PAPER NUMBER		
1624				
NOTIFICATION DATE		DELIVERY MODE		
10/06/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/598,887

**Applicant(s)**

BUSCH-PETERSEN ET AL.

**Examiner**

Brenda L. Coleman

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF 298)  
Paper No(s)/Mail Date 9/14/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

Claims 1-12 are pending in the application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 4-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In evaluating the enablement question, several factors are to be considered. In *re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case has claims, which embrace substituted 3-benzazepines. The scope of claims 4-6 are not adequately enabled solely based on the muscarinic acetylcholine receptor mediated diseases provided in the specification. Claims 4-6 are the method for treating any and all diseases and/or conditions associated with muscarinic acetylcholine receptor, which is not remotely

enabled. The scope of claims 4-6 includes diseases and/or conditions not even known at this time, which may be associated with muscarinic acetylcholine receptor.

HOW TO USE: Claims 4-6 are to the method of use of the compounds of formula (I) where the method is a method of treating a disease, which is responsive to the activity of muscarinic acetylcholine receptor. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. However, the specification provides no definitive evidence to correlate any one disorder selected from those disclosed in the specification with the instantly disclosed 3-benzazepines. No screening protocols are ever described. Thus, no evidence of in vitro effectiveness is seen in the specification for one of the instantly claimed 3-benzazepine derivatives. In general, pharmacological activity is a very unpredictable area. In cases involving physiological activity "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Since this case involves unpredictable in-vivo physiological activities, the scope of the enablement given in the disclosure presented here was found to be low. The specification does not have working examples on the use of the substituted 3-benzazepines. The absence of working examples is one of the factors to be considered in deciding whether the practice of an invention would involve undue experimentation. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of chronic obstructive lung disease, chronic bronchitis, asthma, chronic respiratory obstruction, pulmonary emphysema and allergic rhinitis, etc. Muscarinic acetylcholine

receptor inhibition the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced.

Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied upon are reasonably predictive of in vivo efficacy by those skilled in the art. See *In re Ruskin*, 148 USPQ 221', Ex parte Jovanovics, 211 USPQ 907., MPEP 2164.05(a).

Patent Protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. *Genentech Inc. v. Novo Nordisk* 42 USPQ2d 1001

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1 and 4-12 are vague and indefinite in that it is not known what is meant by (a), (b), (c) and (d) which are not connected to the formulae thus it is not known which formula is (a), (b), etc.
- b. Claims 1 and 4-12 are vague and indefinite in that it is not known what is meant by "Wherein" which is a capital letter indicating the beginning of the claim which is not so.

- c. Claim 2 recites the limitation "2,2-diphenylacetamide" in the nomenclature of the 6<sup>th</sup> species on page 39. There is insufficient antecedent basis for this limitation in the claim.
- d. Claim 2 is vague and indefinite in that it does not end with a period indicating the end of the claim.
- e. Claim 3 recites the limitation "1,1-dimethylethyl-2-oxo-1-  
{[(phenylmethyl)oxy]methyl}ethylcarbamate" in the nomenclature of the 1<sup>st</sup> species on page 40. There is insufficient antecedent basis for this limitation in the claim.
- f. Claim 3 recites the limitation "L-serinamide" in the nomenclature of the 5<sup>th</sup> species on page 40. There is insufficient antecedent basis for this limitation in the claim.
- g. Claim 3 recites the limitation "1,1-dimethylethyl-3-oxopropylthioacetate" in the nomenclature of the 8<sup>th</sup> species on page 40. There is insufficient antecedent basis for this limitation in the claim.
- h. Claim 3 recites the limitation "1,1-diphenylpropanamide" in the nomenclature of the 10<sup>th</sup> species on page 40. There is insufficient antecedent basis for this limitation in the claim.
- i. Claim 3 recites the limitation "1,1-dimethylethyl-4-oxobutylcarbamate" in the nomenclature of the 5<sup>th</sup> species on page 41. There is insufficient antecedent basis for this limitation in the claim.

- j. Claim 3 recites the limitation "1-phenylcyclopentane" in the nomenclature of the 8<sup>th</sup> species on page 41. There is insufficient antecedent basis for this limitation in the claim.
- k. Claim 3 recites the limitation "4-oxo-4-phenyl-2-butenamide" in the nomenclature of the 12<sup>th</sup> species on page 41. There is insufficient antecedent basis for this limitation in the claim.
- l. Claim 3 recites the limitation "1,1-dimethylethyl-2-oxo-1-phenylethylcarbamate" in the nomenclature of the 17<sup>th</sup> species on page 41. There is insufficient antecedent basis for this limitation in the claim.
- m. Claim 3 recites the limitation "1,1-dimethylethyl-2-oxo-1-(3-pyridinylmethyl)ethylcarbamate" in the nomenclature of the 7<sup>th</sup> species on page 42. There is insufficient antecedent basis for this limitation in the claim.
- n. Claim 3 recites the limitation "N<sup>3</sup>-[(4-methylphenyl)sulfonyl]-N<sup>1</sup>-beta-alaninamide" in the nomenclature of the 10<sup>th</sup> species on page 42. There is insufficient antecedent basis for this limitation in the claim.
- o. Claim 3 recites the limitation "2-amino-2-phenylethanamide" in the nomenclature of the 11<sup>th</sup> species on page 42. There is insufficient antecedent basis for this limitation in the claim.
- p. Claim 3 recites the limitation "D-alaninamide" in the nomenclature of the 14<sup>th</sup> species on page 42. There is insufficient antecedent basis for this limitation in the claim.

- q. Claim 3 recites the limitation "3-butenamide" in the nomenclature of the 15<sup>th</sup> species on page 42. There is insufficient antecedent basis for this limitation in the claim.
- r. Claim 3 recites the limitation "butylamide" in the nomenclature of the 2<sup>nd</sup> species on page 43. There is insufficient antecedent basis for this limitation in the claim.
- s. Claim 3 recites the limitation "octylamide" in the nomenclature of the 3<sup>rd</sup> species on page 43. There is insufficient antecedent basis for this limitation in the claim.
- t. Claim 3 is vague and indefinite in that it is not known what is meant by the nomenclature of the 5<sup>th</sup> species is missing a close bracket and an open parenthesis.
- u. Claim 3 recites the limitation "pyrrolidine" in the nomenclature of the 5<sup>th</sup> species on page 43. There is insufficient antecedent basis for this limitation in the claim.
- v. Claim 3 is vague and indefinite in that it is not known what is meant by 2-methyl-quinoline-5-carboxylic acid at the end of the nomenclature of the 5<sup>th</sup> species on page 43. There is insufficient antecedent basis for this limitation in the claim.
- w. Claim 3 is vague and indefinite in that it is not known what is meant by the nomenclature of the 6<sup>th</sup> species on page 43 which appears to be incomplete.



- x. Claim 3 is vague and indefinite in that it is not known what is meant by 5<sup>th</sup> species on page 44 which is a duplicate of the 4<sup>th</sup> species on page 44.
- y. Claims 4-6 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases capable of being mediated by the muscarinic acetylcholine receptor. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug, which has inhibitor properties in vitro, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher

or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus iv or in a time release po formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active in vitro, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are inhibitors in vitro, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property, which the second drug is capable. It is common for a drug, particularly in the treatment of pain, schizophrenia, depression etc., to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to affect a variety of biological targets. In fact, the

development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy, which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

3. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Hadley et al., U.S. 6,605,607. Hadley teaches the compounds and compositions of the compounds of formula (I) where R<sup>1</sup> is acetyl, 1-pyrrolidinylcarbonyl, etc.; q is 1; R<sup>2</sup> is H;

A is 3-(7-aza)indolyl, 4-fluorophenyl-CH=CH-, -CH<sub>2</sub>-(2-benzothiophenyl), 2-acetylphenyl-CH=CH-, 8-(1,4-dihydro-4-oxo)-quinolyl, -CH<sub>2</sub>-(6-(2-amino)benzothiazolyl), 4-acetamidophenyl-CH=CH-, -CH<sub>2</sub>-(3-benzothiophenyl), 1,2-dihydro-2-oxo-quinolin-9-yl-CH=CH-, thiophen-3-yl-CH=CH-, 2-cyanophenyl-CH=CH-, 3-methoxyphenyl-CH=CH-, 3-(3-(5-methyl)-1,2,4-oxadiazolyl)phenyl, 4-fluorophenylmethyl, 3-pyrrolo[2,3-b]pyridyl, etc. as set forth in examples 78-81, 90-93, 99-104, 151, 152, etc.

4. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hadley et al., WO 02/21951. Hadley teaches the compounds and compositions of the compounds of formula (I) where R<sup>1</sup> is acetyl, 1-pyrrolidinylcarbonyl, etc.; q is 1; R<sup>2</sup> is H; A is 3-(7-aza)indolyl, 4-fluorophenyl-CH=CH-, -CH<sub>2</sub>-(2-benzothiophenyl), 2-acetylphenyl-CH=CH-, 8-(1,4-dihydro-4-oxo)-quinolyl, -CH<sub>2</sub>-(6-(2-amino)benzothiazolyl), 4-acetamidophenyl-CH=CH-, -CH<sub>2</sub>-(3-benzothiophenyl), 1,2-dihydro-2-oxo-quinolin-9-yl-CH=CH-, thiophen-3-yl-CH=CH-, 2-cyanophenyl-CH=CH-, 3-methoxyphenyl-CH=CH-, 3-(3-(5-methyl)-1,2,4-oxadiazolyl)phenyl, 4-fluorophenylmethyl, 3-pyrrolo[2,3-b]pyridyl, etc. as set forth in examples 78-81, 90-93, 99-104, 151, 152, etc.

5. Claims 1-4 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The inventors of the instant application have no inventors in common with U.S. Patent No. 6,605,607.

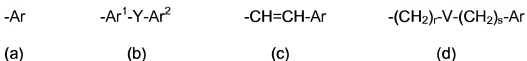
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadley et al., U.S. Patent No. 6,605,607 and WO 00/21951. The generic structure of Hadley encompasses the instantly claimed compounds (see Formula I) as claimed herein. Examples such as compound numbers 1-150 differ only in the nature of the  $R^1$ ,  $R^2$ , q and A substituents of formula I. Column 2, line 23 through column 3, line 13 defines the substituents  $R^1$  represents a substituent selected from: hydrogen or halogen atom; a hydroxy, cyano, nitro, trifluoromethyl, trifluoromethoxy, trifluoromethanesulfonyloxy, pentafluoroethyl,  $C_{1-4}$ alkyl,  $C_{1-4}$ alkoxy, aryl $C_{1-4}$ alkoxy,  $C_{1-4}$ alkylthio,  $C_{1-4}$ alkoxy $C_{1-4}$ alkyl,  $C_{3-6}$ cycloalkyl $C_{1-4}$ alkoxy,  **$C_{1-4}$ alkanoyl**,  $C_{1-4}$ alkoxycarbonyl,  $C_{1-4}$ alkylsulfonyl,  $C_{1-4}$ alkylsulfonyloxy,  $C_{1-4}$ alkylsulfonyl $C_{1-4}$ alkyl, arylsulfonyl, arylsulfonyloxy, arylsulfonyl $C_{1-4}$ alkyl,  $C_{1-4}$ alkylsulfonylamido,  $C_{1-4}$ alkylamido,  $C_{1-4}$ alkylsulfonylamido $C_{1-4}$ alkyl,  $C_{1-4}$ alkylamido $C_{1-4}$ alkyl, arylsulfonylamido, arylcarboxamido, arylsulfonylamido $C_{1-4}$ alkyl, arylcarboxamido $C_{1-4}$ alkyl, **aroyl**, **aroyl $C_{1-4}$ alkyl**, or aroyl $C_{1-4}$ alkanoyl group; a group  $R^3OCO(CH_2)_p$ ,  $R^3CON(R^4)(CH_2)_p$ ,  $R^3R^4NCO(CH_2)_p$  and  $R^3R^4NSO_2(CH_2)_p$ , where each of  $R^3$  and  $R^4$  independently represents a hydrogen atom and a  $C_{1-4}$ alkyl group or  $R^3R^4$  forms part of a  $C_{3-6}$ azacycloalkane or  $C_{3-6}$ (2-oxo)azacycloalkane ring and p represents zero or an integer from 1 to 4; or a group  $Ar^3-Z$ , wherein  $Ar^3$  represents an optionally substituted phenyl ring or an optionally substituted 5- or 6-membered aromatic heterocyclic ring and Z

represents a bond, O, S, or CH<sub>2</sub>; R<sup>2</sup> represents a hydrogen atom or a C<sub>1-4</sub>alkyl group; q is 1 or 2; A represents a group of the formula (a), (b) (c) or (d):



wherein Ar represents an optionally substituted phenyl ring or an optionally substituted 5- or 6-membered aromatic heterocyclic ring; or an optionally substituted bicyclic ring system; Ar<sup>1</sup> and Ar<sup>2</sup> each independently represent an optionally substituted phenyl ring or an optionally substituted 5- or 6-membered aromatic heterocyclic ring; and Y represents a bond, -NHCO-, -CONH-, -CH<sub>2</sub>-, or -(CH<sub>2</sub>)<sub>m</sub>Y<sup>1</sup>(CH<sub>2</sub>)<sub>n</sub>-, wherein Y<sup>1</sup> represents O, S, SO<sub>2</sub>, or CO and m and n each represent zero or 1 such that the sum of m+n is zero or 1; providing that when A represents a group of formula (a), any substituent present in Ar ortho to the carboxamide moiety is necessarily a hydrogen or a methoxy group; r and s independently represent an integer from zero to 3 such that the sum of r and s is equal to an integer from 1 to 4; and V is selected from a group consisting of a bond, O or S; and salts thereof. Compounds of the instant invention are generically embraced by Hadley in view of the interchange ability of R<sup>1</sup>, R<sup>2</sup>, q and A substituents of the 3-benzazepine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example hydroxy for the R<sup>1</sup> substituent of the reference as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17-21 of U.S. Patent No. 6,605,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and composition of the compounds of formula (I) of the instant invention are completely encompassed by the compounds and compositions of the compounds of formula (I) in U.S. '607.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624